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09/554,956	07/11/2000	ROBERT ANDREW BADLEY	IMIN.P-019	6821

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EXAMINER

GABEL, GAILENE

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/15/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/554,956

Applicant(s)

BADLEY ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-16 and 22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-16 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Amendment Entry***

1. Applicant's amendment and response filed 10/29/02 in Paper No. 18 is acknowledged and has been entered. Claims 1 and 7 have been amended. Currently, claims 1-3, 5-16, and 22 are pending and are under examination.

### ***Claim Status***

2. Original claims filed included claims 1-21. Preliminary amendment A requested cancellation of claims 20 and 21, without prejudice; thus claims 1-19 were pending. Amendment C requested cancellation of claims 4 and non-elected claims 17-19, and addition of claim 22; thus, claims 1-3, 5-16, and 22 were pending. No addition or cancellation of claims has been requested by Applicant since. Accordingly, claims 1-3, 5-16, and 22 remain pending and under examination.

### **Rejection Withdrawn**

3. In light of Applicant's argument, the rejection of claim 12 under 35 U.S.C. 102(b) as being anticipated by Partin et al. (US 5,082,630) is hereby, withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 1-3, 5-16, and 22, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in reciting, "a species capable of producing a detectable signal" because it is unclear what is encompassed by the term "species" or how it relates structurally or functionally to the recited "displaceable moiety" and "capture moiety". It is further unclear as recited how the claimed "species" is enabled to produce a signal, i.e. fluorescence as a result of binding between members of a binding partner, for example. Claim 1 also fails to recite a positive limitation in the claim in reciting, "capable of".

Claim 1 is further vague and indefinite in reciting, "treating the species capable of producing a detectable signal to generate the signal" because it is unclear what is encompassed by the term "treating" as used in the claim, i.e. simultaneously incorporating a label, for example.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 7-10, and 13-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Schramm et al. (WO 91/05262) for reason of record.

Schramm et al. disclose a method of detecting the presence of an analyte in a sample comprising providing a first surface having a displaceable moiety reversibly immobilized, exposing the first surface to a sample wherein any analyte in the sample displaces the displaceable moiety, and detecting a signal. Schramm et al. teach contacting the first surface, upon which a displaceable moiety such as an antibody or analyte has been reversibly bound, with a sample wherein analyte in the sample displaces the reversibly bound moiety causing the displaced moiety to bind to a second surface upon which a specific antibody is bound and detecting the signal which can be produced by fluorescence or enzyme labels. Schramm et al. also teach that the two surfaces can be on separate or same supports and that planar, porous, or particulate surfaces may be used (see Abstract, especially page 4, line 32 to page 5, line 14, page 8, line 20 to page 9, line 19, and page 11, lines 5-25).

6. Claims 1-3, 7-8, 11, and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Partin et al. (US 5,082,630).

Partin et al. disclose a fiber optic detector for use in immune testing. In practice, Partin et al. disclose coating a distal end of an optical fiber or waveguide (first surface) with antibody, then saturating the fiber with fluorescent-tagged drug derivative, i.e. antigen (displaceable moiety). Thereafter, the fiber is exposed to an airborne sample of the analyte, i.e. drug, to be detected. If the analyte is present, the analyte molecules displace some of the bound, fluorescent-tagged derivative, resulting in a decrease (modulation) in signal as detected by a detecting diode. The extent of the decrease is

proportional to the concentration of drug molecules in the surrounding environment.  
See column 4, lines 49-64 and column 4).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 6 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm et al. (WO 91/05262) or Partin et al. (US 5,082,630).

Schramm et al. and Partin et al. have been discussed supra. Schramm et al. and Partin et al. differ from the instant invention in failing to disclose specifically using a mimitope in claim 6 as a displaceable moiety or in claim 22 as an intervening moiety.

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Badley et al. disclose using mimitopes or analogues of analyte in displacement assays wherein the mimitope is immobilized reversibly on a solid support and wherein in the presence of analyte in a sample, the analyte displaces the mimitope, causing a reduction in mass of material immobilized on the solid support. Change in mass on the solid support is measured by acoustic wave or evanescent wave sensors. See especially column 2, line 23 to column 6, line 62.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the intervening moiety or the displaceable moiety in the method of Schramm or Partin, with mimitopes or analogue of analyte as taught by Badley because Badley specifically taught application of these mimitopes in displacement assays such as in the methods of Schramm and Partin.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm et al. (WO 91/05262) or Partin et al. (US 5,082,630).

Schramm et al. and Partin et al. have been discussed supra. Schramm et al. and Partin et al. differ from the instant invention in failing to disclose specifically using fusion protein in claim 5 as a displaceable moiety.

Presta et al. disclose using fusion proteins (chimeric proteins) in competitive displacement assays. Specifically, Presta et al. tested binding specificity of fusion proteins in a cellular environment, wherein the competitive displacement assay was done with iodinated neurotrophins.

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It would have been obvious to one of ordinary skill in the art at the time of the instant invention to substitute the intervening moiety or the displaceable moiety in the method of Schramm or Partin, with fusion or chimeric proteins as taught by Presta because Presta specifically taught application of fusion proteins in displacement assays such as in the methods of Schramm and Partin.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schramm et al. (WO 91/05262) or Partin et al. (US 5,082,630) in view Alcock et al. (US 5,736,188).

Schramm et al. and Partin et al. have been discussed supra. Schramm et al. and Partin et al. differ from the instant invention in failing to disclose that the capture of the displaceable moiety modulates an electrochemical property of the capture moiety, which modulation comprises a detectable signal.

Alcock et al. disclose capture moieties, i.e. receptors, immobilized in a detection surface that is used in a displacement assay format wherein displaceable moieties, i.e. synthetic peptide bound to labelled analyte, are immobilized on an electrode area and sample analyte will displace the labelled analyte as the sample flows over the electrode area. The amount displaced will be proportional to the amount of analyte in the sample. The remaining label is then detected electrochemically upon delivery of a substrate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to electrochemically detect labels such as taught by Alcock present in the capture moieties immobilized on the detection surface as taught in the



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displacement assays of Schramm or Partin, because Alcock specifically taught that electrochemical detection can be applied in any displacement assay.

### ***Response to Arguments***

10. Applicant's arguments filed 4/30/01 have been fully considered but they are not persuasive.

A) Applicant argues that claims 1-3, 7-10, and 13-16 are not anticipated by Schramm et al. because claim 1 requires the generation and detection of a signal which cannot be generated unless and until the displaceable moiety is captured on the second surface. Applicant specifically point out that the signal generating moiety in Schramm is an enzyme-analyte conjugate which produces a detectable signal in the presence of appropriate substrate, whether bound to a solid surface or not, and regardless of the location to which it is bound. According to Applicant, it is not the generation of the signal but rather the location of the signal that is diagnostic, since the signal may be developed at either binding location since a detectable signal is generated in Schramm et al. whether analyte is present or not.

In response, the claimed invention at lines 9-16 specifically relies upon an interaction that takes place in the second surface in the presence of analyte, wherein the second surface bears a capture moiety upon which the displaceable moiety from the first surface is captured, thus causing the generation of a signal at the second surface. Accordingly, contrary to Applicant's contention, Schramm et al., indeed, disclose a same embodiment wherein in the presence of analyte, the displaceable moiety which

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carries a signal generating moiety is displaced by the analyte in the first surface, then captured by the second surface bearing a capture moiety upon which the displaceable moiety from the first surface is captured, thus causing the generation of a signal at the second surface. The detectable signal relied upon on both the claimed invention and prior art is the detectable signal generated upon capture of the displaceable moiety in the second surface. Further, in as far as the enzyme-analyte conjugate, i.e.

displaceable moiety in the teaching of Schramm et al, which produces a detectable signal in the presence of appropriate substrate, the detectable signal relied upon is the signal generated or modulated upon capture of the displaceable moiety in the second surface. Such embodiment is likewise encompassed in Applicant's disclosure at page 7, second full paragraph. Accordingly, Accordingly, the rejection of claims 1-3, 7-10, and 13-16 as being anticipated by Schramm et al. is maintained.

B) Applicant argues that claims 1-3, 7-8, 11 and 14-16 are not anticipated by Partin et al. because in Partin et al., the presence of a drug is detected by means of a reduction in fluorescence signal intensity when fluorescently labeled drug is displaced from a detection site. Applicant specifically contends that the fluorescent signal is not a signal which can be generated only when the sample is bound since fluorescence is observed, i.e. from the label on non-displaced drug, or present whether or not the drug is bound.

In response, the claimed invention at lines 9-16 specifically relies upon an interaction that takes place in the second surface in the presence of analyte, wherein

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the second surface bears a capture moiety upon which the displaceable moiety is captured, thus causing the generation of a signal at the second surface. Accordingly, contrary to Applicant's contention, Partin et al., indeed, disclose a fiber optic detector wherein in the presence of analyte, the displaceable moiety which carries a signal generating moiety is displaced by the analyte, thus causing modulation of the signal at the surface of the fiber optic detector. The detectable signal relied upon on both the claimed invention and prior art is the detectable signal generated upon in the surface of the detector. Accordingly, the rejection of claims 1-3, 7-8, 11, and 14-16 as being anticipated by Partin et al. is maintained.

11. For reasons aforementioned, no claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 4:00 PM and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 308-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gailene R. Gabel

January 13, 2002 *gg*



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP ~~1800~~ 1641